Also in the item (3) of the Action, the Examiner suggests that the claims should be revised to exclude the presence of TGFβ1 and TGFβ2. Respectfully, statutory basis for the suggestion is not seen. While TGFβ1 and TGFβ2 are known to be fibrotic (and therefore antagonistic to the anti-fibrotic effects of TGFβ3), the defining feature of the claims is that there is sufficient TGFβ3 to have an anti-fibrotic effect. Although no amendment is believed necessary, the claims have been revised in a manner that is believed to moot the Examiner's concerns.

Claims 57, 58, 60, 65, 66 and 68 (and claims depending therefrom) stand rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Withdrawal of the rejection is believed to be in order for the reasons that follow.

In rejecting the claims as indefinite, the Examiner cites In re Gunn, 190 USPQ 402 (CCPA 1976) and In re Donohue, 193 USPQ 136 (CCPA 1997) to support his position. Respectfully, neither of these decisions is believed to be relevant. Thus issue in Gunn and Donohue was one of enablement, not indefiniteness, as is the case here.

The language of the present claims is earnestly believed to define the invention with all the clarity that the law requires. Indeed, the Examiner has not indicated why one would have any difficulty determining whether any particular activity fell inside or outside the scope of the claims. The Examiner in fact

appears to acknowledge that the claims satisfy the requirements of the second paragraph of 35 USC 112 when he states that he "does not dispute that assays could be used to determine which factors are anti-fibrotic under particular assay conditions". Having performed the assays and obtained the results, there would be no doubt as to whether the claim requirements were met.

In view of the above, reconsideration is requested.

Claims 56-71 stand rejected under 35 USC 112, first paragraph, as allegedly being non-enabled. Withdrawal of the rejection is submitted to be in order for the reasons that follow.

As the rejection is understood, it is based on an alleged lack of enablement of the "anti-fibrotic agents". That being the case, it is believed that the inclusion in the rejection of claims 56, 62, 63, 64, 70 and 71 is in error and clarification is requested.

Insofar as the "anti-fibrotic agents" are concerned, the Examiner is reminded that all of the claims are method claims. The specific structure of the anti-fibrotic agent is not critical to Applicants' method. Indeed, it is entirely appropriate that the claims encompass the use of anti-fibrotic agents not yet invented.

The Examiner's concerns regarding the functional language used to define the anti-fibrotic agents may have merit if the

claims were drawn to such agents or compositions comprising same. However, and as indicated above, the functional recitations are entirely appropriate in the context of method claims and the Examiner is urged to reconsider his position in this regard.

With respect to (C) and (D) of item (6) of the Action, attention is directed to the fact that oligonucleotides and ribozymes represent well known agents that may be used to inhibit the activity or production of a target protein. A skilled person would be familiar with these kinds of agents and it would only require simple workman-like development to produce the agents for use according to the method of the invention.

The transfection of cells and the effects of nucleases (item 6(C)) represent developmental issues that do not detract from the usefulness of oligonucleotides and ribozymes. The detailed Example of the specification may relate to neutralizing antibodies, however, the Examiner is reminded that it is not necessary to provide substantiating data for every alternative covered by a claim. In this respect, ribozymes and oligonucleotides represent well known alternatives to neutralizing antibodies and Applicants, therefore, submit that they are entitled to protection for these agents in the context of the present method claims without the need for actual evidence of their effectiveness.

As for item (6(D)), the Examiner is reminded that the claims require the inhibition of fibrosis (claim 56) or reduction of scarring (claim 64) as a result of the provision of a sufficient amount of TGFβ_3. Accordingly, no need is seen for a limitation to the effect that the agent does not significantly affect TGFβ3.

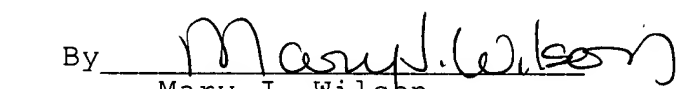
Reconsideration is requested.

Claims 56, 62, 63, 64, 70 and 71 stand rejected under 35 USC 103 as allegedly being obvious over Cerletti et al. Withdrawal of the rejection is believed to be in order in view of the above noted claim revisions introduced for purposes of clarity. Reconsideration is requested.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

NIXON & VANDERHYE, P.C.

By 
Mary J. Wilson
Reg. No. 32,955

MJW:tat

1100 North Glebe Road
8th Floor
Arlington, Virginia 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100